

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-9, in the reply filed on 1/12/2008 is acknowledged.

Status of Claims

2. Claims 1-11 are pending. Claims 10-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/12/2008. Claims 1-9 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "reconstituted form" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "reconstituted composition" in line 2. There is insufficient antecedent basis for this limitation in the claim. This rejection also affects claim 8 for it recites a dependency to claim 7.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cammack et al.¹

The claims are directed to a composition comprising an antigen in above 15mM of NaCl and a carbohydrate that exhibit acidic moieties. Claim 2, which depends on claim 1, requires the acidic moieties to be a carboxylic moiety. Claim 3, which depends on claim 2, requires the carbohydrate to be selected from the group consisting of lactobionic acid, gluconic acid, glucuronic acid, galacturonic acid and galactaric acid. Claim 4, which depends on claim 1, requires the concentration of NaCl to be at least 30 mM. Claim 5, which depends on claim 1, requires the composition be in spray/vacuum or freeze dried form. Claim 9, which depends on claim 1, requires the antigen to be influenza virus.

Cammack et al. teaches a composition comprising an antigen, NaCl and a carbohydrate that exhibit acidic moieties. [Tables V-IX, pages 272-278, in particular.] The carbohydrate with acidic moieties that Cammack et al. teaches is calcium lactobionate, which is a salt form of lactobionic acid. The antigen is the influenza virus.

¹ Cammack, K. A. and Adams, G. D. J. (1985) Formulation and storage, in *Animal Cell Biotechnology*, vol. 2 (Spiers, R. E. and Griffiths, J. B., eds.), Academic Press, London, pp. 251–288.

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The composition of Cammack et al. is in form suitable for spray/vacuum or freeze dried. Cammack et al. also teaches the composition in freeze dried form. Cammack et al. teaches the use of .9% and .85% of NaCl. The noted % solution of NaCl equals to .15 M and .14 M, respectively. $[(\% \text{ solution} * 10) / \text{Formula weight of } 58.44 \text{ for NaCl} = _ \text{ M.}]$ The concentration of NaCl taught by Cammack et al. is above .15 mM and at least .30 mM. In the instant case, Cammack et al. teaches the claimed composition. Hence, the claimed invention is anticipated by Cammack et al.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cammack et al., as applied to claim 1, in view of Bomford, R.²

Claim 6 requires the composition to be in reconstituted form. Claim 7 requires the composition be reconstituted with an adjuvant. Claim 8, which depends on claim 7, requires the adjuvant to be oil-in-water emulsion, 3D-MPL, CpG, QS21 or a mixture of two or more thereof.

The significance of Cammack et al., as applied to claim 1, is provided above. Cammack et al. did not reconstitute his freeze dried composition with an adjuvant.

² Bomford (1985) Adjuvants, in Animal Cell Biotechnology, vol. 2 (Spiers, R. E. and Griffiths, J. B., eds.), Academic Press, London, pp. 235-250.

However, Bomford, R. teaches the use of adjuvants such as oil in water emulsions to enhance the immune response induced by antigens. Hence, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to reconstitute the antigenic composition of Cammack et al. with an adjuvant, including oil in water emulsion. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to enhance the immune response induced by the antigen. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of the use of adjuvant with antigenic compositions are routinely practiced in the art.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571)272-0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Emily Le/
Patent Examiner, Art Unit 1648

/E. L./